

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 225

Dispensing of Controlled Substances

SPONSOR(S): Legg

TIED BILLS:

IDEN./SIM. BILLS:

	REFERENCE	ACTION	ANALYST	STAFF DIRECTOR
1)	<u>Health Care Regulation Policy Committee</u>	<u></u>	<u>Calamas</u>	<u>Calamas</u>
2)	<u>Health & Family Services Policy Council</u>	<u></u>	<u></u>	<u></u>
3)	<u></u>	<u></u>	<u></u>	<u></u>
4)	<u></u>	<u></u>	<u></u>	<u></u>
5)	<u></u>	<u></u>	<u></u>	<u></u>

SUMMARY ANALYSIS

House Bill 225 amends s. 465.0276, F.S. to prohibit practitioners from dispensing more than a 72-hour supply of controlled substances listed in Schedules II, III, and IV. The bill does not prohibit physicians from prescribing controlled substances. Under the bill's provisions, patients who receive prescriptions for controlled substances would fill them at pharmacies, rather than in physician offices or clinics.

The bill exempts controlled substances dispensed in the health care system of the Department of Corrections. Hospitals and other facilities dispensing through institutional pharmacies would be unaffected by the bill.

The bill appears to have no fiscal impact on state or local government.

The bill provides an effective date of July 1, 2010.

HOUSE PRINCIPLES

Members are encouraged to evaluate proposed legislation in light of the following guiding principles of the House of Representatives

- Balance the state budget.
- Create a legal and regulatory environment that fosters economic growth and job creation.
- Lower the tax burden on families and businesses.
- Reverse or restrain the growth of government.
- Promote public safety.
- Promote educational accountability, excellence, and choice.
- Foster respect for the family and for innocent human life.
- Protect Florida's natural beauty.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Current Situation

Controlled Substances Dispensing

Chapter 893, F.S., sets forth the Florida Comprehensive Drug Abuse Prevention and Control Act.¹ Controlled substances are classified into five schedules in order to regulate the manufacture, distribution, preparation, and dispensing of the substances. Substances in Schedule I have a high potential for abuse and have no currently accepted medical use in the United States. Schedule II drugs have a high potential for abuse and a severely restricted medical use. Cocaine and morphine are examples of Schedule II drugs. Schedule III controlled substances have less potential for abuse than Schedule I or Schedule II substances and have some accepted medical use. Substances listed in Schedule III include anabolic steroids, codeine, and derivatives of barbituric acid. Schedule IV and Schedule V substances have a low potential for abuse, compared to substances in Schedules I, II, and III, and currently have accepted medical use. Substances in Schedule IV include phenobarbital, librium, and valium. Substances in Schedule V include certain stimulants and narcotic compounds.

Pharmacists and Pharmacies

Section 893.04, F.S., authorizes a pharmacist, in good faith and in the course of professional practice to dispense controlled substances upon a written or oral prescription under specified conditions:

- An oral prescription must be promptly reduced to writing by the pharmacist;
- The written prescription must be dated and signed by the prescribing practitioner on the date issued; and
- The face of the prescription or written record for the controlled substance must include:
 - The full name and address of the person for whom, or the owner of the animal for which, the controlled substance is dispensed;
 - The full name and address of the prescribing practitioner and the prescriber's federal controlled substance registry number;
 - If the prescription is for an animal, the species of animal for which the controlled substance is prescribed;

¹ See, *also*, the federal Controlled Substances Act, 21 U.S.C. 812.

- The name of the controlled substance prescribed and the strength, quantity, and directions for the use thereof;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filed; and
- The initials of the pharmacist filling the prescription and the date filled.

Section 893.04(1)(d), F.S., requires the pharmacy in which a prescription for controlled substances is filled to retain the prescription on file for a period of 2 years. The original container in which a controlled substance is dispensed must bear a label with the following information:

- The name and address of the pharmacy from which the controlled substance was dispensed;
- The date on which the prescription for the controlled substance was filled;
- The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled;
- The name of the prescribing practitioner;
- The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed;
- The directions for the use of the controlled substance prescribed in the prescription; and
- A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

Chapter 893, F.S., imposes other limitations on controlled substance prescriptions. A prescription for a Schedule II controlled substance may be dispensed only upon a written prescription of a practitioner, except in an emergency situation, as defined by rule of the department. No prescription for a Schedule II controlled substance may be refilled.² No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.³ A pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of a prescribed medication, except for those listed in Schedule II.⁴

In addition to these requirements for dispensing controlled substances, pharmacies must comply with regulations that apply to all dispensing. A pharmacy cannot dispense a medication if the prescription is not based on a “valid practitioner-patient relationship”. Such a relationship includes “a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed”.⁵ Department of Health rules apply this standard to controlled substances:⁶

The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

- (a) Frequent loss of controlled substance medications,
- (b) Only controlled substance medications are prescribed for a patient,
- (c) One person presents controlled substance prescriptions with different patient names,
- (d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,
- (e) Patient always pays cash and always insists on brand name product.

If any of those criteria are met the pharmacy must copy the patient’s photo identification for its records, and confirm the prescription with the physician. The Department of Health inspects pharmacies at least once a year to ensure compliance with statutory and regulatory requirements.⁷

² s. 893.04(1)(f), F.S.

³ s. 893.04(1)(g), F.S.

⁴ See 21 C.F.R. 1306.11(d)(1), which provides that in an emergency situation, a pharmacist may dispense a Schedule II controlled substance upon receiving oral authorization of a prescribing practitioner if the quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period.

⁵ S. 465.023(1)(h), F.S.

⁶ Rule 64B16-27.831, F.A.C.

⁷ Rule 64B16-28.101, F.A.C.

Physicians

Section 893.05, F.S., allows a practitioner, in good faith and in the course of professional practice only, to prescribe, administer, dispense, mix, or otherwise prepare a controlled substance. "Practitioner" means a licensed medical physician, a licensed dentist, a licensed veterinarian, a licensed osteopathic physician, a licensed naturopathic physician, or a licensed podiatrist, if such practitioner holds a valid federal controlled substance registry number.⁸ Physician dispensing is regulated by the relevant medical boards within the Department of Health.

In order to dispense medications, rather than just prescribe them, physicians must register with the Department and pay a fee of \$100.⁹ Physicians who only dispense complimentary medications, and who receive no direct or indirect payment or remuneration for the medications, are not required to register.¹⁰

The Department must inspect any facility in which a physician dispenses medication, such as a physician office or medical clinic, with the same frequency as it inspects pharmacies, that is, at least once a year (see above).¹¹ Dispensing physicians are required to comply with all state and federal laws and regulations applicable to pharmacists and pharmacies (see above).¹² For example, a pharmacy is not permitted to dispense a drug if the prescription is not based on a valid practitioner-patient relationship, which requires a patient history and a physical examination adequate to establish the diagnosis. This requirement applies to dispensing physicians as well.

Dispensing Prohibitions

Currently, Florida law allows registered physicians to dispense any prescribed drug. Other states have varying degrees of regulation. 20 states allow dispensing and require some form of dispensing license.¹³ 23 states allow dispensing do not require any license. One state allows dispensing, and requires a license to dispense controlled substances.

Some states prohibit physician dispensing entirely.¹⁴ Montana, Texas and Utah prohibit all physician dispensing; Massachusetts allows physicians to dispense only a 72-hour supply for emergencies. These states do not distinguish between controlled substances and other medications; all are included in the prohibition.

Prescription Drug Diversion and Abuse

According to the Substance Abuse and Mental Health Services Administration, more than 6.3 million Americans reported using prescription drugs for nonmedical reasons in 2003.¹⁵ Most people who take prescription medications take them responsibly; however, the nonmedical use or abuse of prescription drugs remains a serious public health concern in the United States. Certain prescription drugs – opioid substances, central nervous system depressants, and stimulants – when abused can alter the brain's activity and lead to dependence and possible addiction.

Prescription drug abuse also occurs when a person illegally obtains a legal prescription drug for nonmedical use. People obtain these drugs in a variety of ways, including "doctor shopping," in which the person continually switches physicians so that they can obtain enough of the drug to feed their addiction. By frequently switching physicians, the doctors are unaware that the patient has already been prescribed

⁸ S. 893.02, F.S.

⁹ S. 465.0276(2)(a), F.S.; Rule 64B8-3.006, F.A.C.

¹⁰ S. 465.0276(5), F.S.

¹¹ S. 465.0276(3), F.S.

¹² S. 465.0276(2)(a), F.S.

¹³ Dispensing Regulations by State, American Academy of Urgent Care Medicine, *available at* <http://aaucm.org/Professionals/MedicalClinicalNews/DispensingRegulations/default.aspx> (last viewed January 30, 2010).

¹⁴ *Id.*

¹⁵ Overview of Findings from the 2003 National Survey on Drug Use and Health, *see* <http://oas.samhsa.gov/nhsda/2k3nsduh/2k3Overview.htm> (last viewed January 30, 2010).

the same drug and may be abusing it. Some physicians prescribe and dispense medically unjustifiable amounts of controlled substances, and are aware of their patients' abuse.¹⁶

Use of prescription pain relievers without a doctor's prescription or only for the experience or feeling they cause ("nonmedical" use) is, after marijuana use, the second most common form of illicit drug use in the United States.¹⁷ According to the Drug Abuse Warning Network (DAWN), approximately 324,000 emergency department visits in 2006 involved the nonmedical use of pain relievers (including both prescription and over-the-counter pain medications).¹⁸

According to research by the National Institute on Drug Abuse¹⁹, the three most abused classes of prescription drugs are:

- Opioids, used to treat pain. Examples include codeine (Schedules II, III, V), oxycodone (OxyContin, Percocet – Schedule II), and morphine (Kadian, Avinza -Schedule II);
- Central nervous system depressants, used to treat anxiety and sleep disorders. Examples include barbiturates (Mebaral, Nembutal) and benzodiazepines (Valium, Xanax) (all in Schedule IV); and
- Stimulants, used to treat ADHD, narcolepsy, and obesity. Examples include dextroamphetamine (Dexedrine, Adderall) and methylphenidate (Ritalin, Concerta) (all in Schedule II).

The most commonly abused drugs (highlighted below) are found in all four prescribable controlled substance Schedules.²⁰

Substance	Other Names
Schedule II - high potential for abuse; severely restricted medical use	
1-Phenylcyclohexylamine	Precursor of PCP
1-Piperidinocyclohexanecarbonitrile	PCC, precursor of PCP
Alfentanil	Alfenta
Alphaprodine	Nisentil
Amobarbital	Amytal, Tuinal
Amphetamine	Dexedrine, Biphphetamine
Anileridine	Leritine
Benzoyllecgonine	Cocaine metabolite
Bezitamide	Burgodin
Carfentanil	Wildnil
Coca Leaves	
Cocaine	Methyl benzoyllecgonine, Crack
Codeine	Morphine methyl ester, methyl morphine

¹⁶ See, Press Release, U.S. Att'y No. Dist. Fla., Destin Physician Sentenced to Life Imprisonment for Illegal Distribution of Controlled Substances, available at <http://www.justice.gov/usao/fln/press%20releases/2010/jan/webb.html> (last viewed January 30, 2010); The Oxycontin Express (Vanguard, 2009) available at <http://www.hulu.com/watch/100279/vanguard-the-oxycontin-express> (last viewed January 30, 2010).

¹⁷ Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Results from the 2007 National Survey on Drug Use and Health: National findings (DHHS Publication No. SMA 08-4343, NSDUH Series H-34) (2008), see <http://oas.samhsa.gov/p0000016.htm> (last viewed January 30, 2010); cited in, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, see <http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm> (last viewed January 30, 2010).

¹⁸ Substance Abuse and Mental Health Services Administration, Office of Applied Studies, Drug Abuse Warning Network, 2006: National Estimates of Drug-Related Emergency Department Visits, (August 2008), see <http://dawninfo.samhsa.gov/files/ED2006/DAWN2K6ED.pdf> (last viewed January 30, 2010), cited in, The NSDUH Report, Trends in Nonmedical Use of Prescription Pain Relievers: 2002 to 2007, Feb. 5, 2009, see <http://www.oas.samhsa.gov/2k9/painRelievers/nonmedicalTrends.cfm> (last viewed January 30, 2010).

¹⁹ National Institutes of Health, National Institute on Drug Abuse, available at, <http://www.drugabuse.gov/Researchreports/Prescription/prescription2.html>.

²⁰ National Institutes of Health, National Institute on Drug Abuse, available at, <http://www.drugabuse.gov/DrugPages/DrugsofAbuse.html> (last viewed January 30, 2010); U.S. Drug Enforcement Administration, available at, <http://www.justice.gov/dea/pubs/scheduling.html> (last viewed January 30, 2010). This is a very basic list which describes the parent chemicals, not the salts, isomers and salts of isomers, esters, ethers and derivatives which may also be controlled substances.

Dextropropoxyphene, bulk (non-dosage forms)	Propoxyphene
Dihydrocodeine	Didrate, Parzone
Diphenoxylate	
Diprenorphine	M50-50
Ecgonine	Cocaine precursor, in Coca leaves
Ethylmorphine	Dionin
Etorphine HCl	M 99
Fentanyl	Innovar, Sublimaze, Duragesic
Glutethimide	Doriden, Dorimide
Hydrocodone	dihydrocodeinone
Hydromorphone	Dilaudid, dihydromorphinone
Isomethadone	Isoamidone
Levo-alphaacetylmethadol	LAAM, long acting methadone, levomethadyl acetate
Levomethorphan	
Levorphanol	Levo-Dromoran
Meperidine	Demerol, Mepergan, pethidine
Meperidine intermediate-A	Meperidine precursor
Meperidine intermediate-B	Meperidine precursor
Meperidine intermediate-C	Meperidine precursor
Metazocine	
Methadone	Dolophine, Methadose, Amidone
Methadone intermediate	Methadone precursor
Methamphetamine	Desoxyn, D-desoxyephedrine, ICE, Crank, Speed
Methylphenidate	Ritalin
Metopon	
Moramide-intermediate	
Morphine	MS Contin, Roxanol, Duramorph, RMS, MSIR
Nabilone	Cesamet
Opium extracts	
Opium fluid extract	
Opium poppy	Papaver somniferum
Opium tincture	Laudanum
Opium, granulated	Granulated opium
Opium, powdered	Powdered Opium
Opium, raw	Raw opium, gum opium
Oxycodone	OxyContin, Percocet, Tylox, Roxicodone, Roxicet,
Oxymorphone	Numorphan
Pentobarbital	Nembutal
Phenazocine	Narphen, Prinadol
Phencyclidine	PCP, Sernylan
Phenmetrazine	Preludin
Phenylacetone	P2P, phenyl-2-propanone, benzyl methyl ketone
Piminodine	
Poppy Straw	Opium poppy capsules, poppy heads
Poppy Straw Concentrate	Concentrate of Poppy Straw, CPS
Racemethorphan	
Racemorphan	Dromoran
Remifentanil	Ultiva
Secobarbital	Seconal, Tuinal
Sufentanil	Sufenta
Thebaine	Precursor of many narcotics

Schedule III - (less potential for abuse than Schedules I or II substances; some accepted medical use)

Amobarbital & noncontrolled active ingred.	Amobarbital/ephedrine capsules
Amobarbital suppository dosage form	
Anabolic steroids	"Body Building" drugs
Aprobarbital	Alurate
Barbituric acid derivative	Barbiturates not specifically listed
Benzphetamine	Didrex, Inapetyl
Boldenone	Equipoise, Parenabol, Vebonol, dehydrotestosterone
Buprenorphine	Buprenex, Temgesic
Butabarbital	Butisol, Butibel
Butalbital	Fiorinal, Butalbital with aspirin
Chlorhexadol	Mechloral, Mecoral, Medodorm, Chloralodol
Chlorotestosterone (same as clostebol)	if 4-chlorotestosterone then clostebol
Chlorphentermine	Pre-Sate, Lucofen, Apsedon, Desopimon
Clortermine	Voranil
Clostebol	Alfa-Trofodermin, Clostene, 4-chlorotestosterone
Codeine & isoquinoline alkaloid 90 mg/du	Codeine with papaverine or noscapine
Codeine combination product 90 mg/du	Empirin, Fiorinal, Tylenol, ASA or APAP w/codeine
Dehydrochloromethyltestosterone	Oral-Turinabol
Dihydrocodeine combination product 90 mg/du	Synalgos-DC, Compal
Dihydrotestosterone (same as stanolone)	see stanolone
Dronabinol in sesame oil in soft gelatin capsule	Marinol, synthetic THC in sesame oil/soft gelatin
Drostanolone	Drolban, Masterid, Permastril
Ethylestrenol	Maxibolin, Orabolin, Durabolin-O, Duraboral
Ethylmorphine combination product 15 mg/du	
Fluoxymesterone	Anadroid-F, Halotestin, Ora-Testryl
Formebolone (incorrect spelling in law)	Esiclene, Hubernol
Hydrocodone & isoquinoline alkaloid 15 mg/du	Dihydrocodeinone+papaverine or noscapine
Hydrocodone combination product 15 mg/du	Tussionex, Tussend, Lortab, Vicodin, Hycodan, Anexsia ++
Ketamine	Ketaset, Ketalar, Special K, K
Lysergic acid	LSD precursor
Lysergic acid amide	LSD precursor
Mesterolone	Proviron
Methandienone (see Methandrostenolone)	
Methandranone	
Methandriol	Sinesex, Stenediol, Troformone
Methandrostenolone	Dianabol, Metabolina, Nerobol, Perbolin
Methenolone	Primobolan, Primobolan Depot, Primobolan S
Methyltestosterone	Android, Oreton, Testred, Virilon
Methypylon	Noludar
Mibolerone	Cheque
Morphine combination product/50 mg/100 ml or gm	
Nalorphine	Nalline
Nandrolone	Deca-Durabolin, Durabolin, Durabolin-50
Norethandrolone	Nilevar, Solevar
Opium combination product 25 mg/du	Paregoric, other combination products
Oxandrolone	Anavar, Lonavar, Provitar, Vasorome
Oxymesterone	Anamidol, Balnimax, Oranabol, Oranabol 10
Oxymetholone	Anadrol-50, Adroyd, Anapolon, Anasteron, Pardroyd
Pentobarbital & noncontrolled active ingred.	FP-3
Pentobarbital suppository dosage form	WANS
Phendimetrazine	Plegine, Prelu-2, Bontril, Melfiat, Statobex

Secobarbital & noncontrolled active ingred	various
Secobarbital suppository dosage form	various
Stanolone	Anabolex, Andractim, Pesomax, dihydrotestosterone
Stanozolol	Winstrol, Winstrol-V
Stimulant compounds previously excepted	Mediatric
Sulfondiethylmethane	
Sulfonethylmethane	
Sulfonmethane	
Talbutal	Lotusate
Testolactone	Teslac
Testosterone	Android-T, Androlan, Depotest, Delatestyl
Thiamylal	Surital
Thiopental	Pentothal
Tiletamine & Zolazepam Combination Product	Telazol
Trenbolone	Finaplix-S, Finajet, Parabolan
Vinbarbital	Delvinal, vinbarbitone
Schedule IV - (less potential for abuse than Schedules I, II, or III substances; some accepted medical use)	
Alprazolam	Xanax
Barbital	Veronal, Plexonal, barbitone
Bromazepam	Lexotan, Lexatin, Lexotamil
Butorphanol	Stadol, Stadol NS, Torbugesic, Torbutrol
Camazepam	Albego, Limpidon, Paxor
Cathine	Constituent of "Khat" plant
Chloral betaine	Beta Chlor
Chloral hydrate	Noctec
Chlordiazepoxide	Librium, Libritabs, Limbitrol, SK-Lygen
Clobazam	Urbadan, Urbanyl
Clonazepam	Klonopin, Clonopin
Clorazepate	Tranxene
Clotiazepam	Trecalmo, Rize
Cloxazolam	Enadel, Sepazon, Tolestan
Delorazepam	
Dexfenfluramine	Redux
Dextropropoxyphene dosage forms	Darvon, propoxyphene, Darvocet, Dolene, Propacet
Diazepam	Valium, Valrelease
Dichloralphenazone	Midrin, dichloralantipyrine
Diethylpropion	Tenuate, Tepamil
Difenoxin 1 mg/25 ug AtSO4/du	Motofen
Estazolam	ProSom, Domnamid, Eurodin, Nuctalon
Ethchlorvynol	Placidyl
Ethinamate	Valmid, Valamin
Ethyl loflazepate	
Fencamfamin	Reactivan
Fenfluramine	Pondimin, Ponderal
Fenproporex	Gacilin, Solvolip
Fludiazepam	
Flunitrazepam	Rohypnol, Narcozep, Darkene, Roipnol
Flurazepam	Dalmane
Halazepam	Paxipam
Haloxazolam	
Ketazolam	Anxon, Loftran, Solatran, Contamex
Loprazolam	

Lorazepam	Ativan
Lormetazepam	Noctamid
Mazindol	Sanorex, Mazanor
Mebutamate	Capla
Medazepam	Nobrium
Mefenorex	Anorexic, Amexate, Doracil, Pondinil
Meprobamate	Miltown, Equanil, Deprol, Equagesic, Meprospan
Methohexital	Brevital
Methylphenobarbital (mephobarbital)	Mebaral, mephobarbital
Midazolam	Versed
Modafinil	Provigil
Nimetazepam	Erimin
Nitrazepam	Mogadon
Nordiazepam	Nordazepam, Demadar, Madar
Oxazepam	Serax, Serenid-D
Oxazolam	Serenal, Converal
Paraldehyde	Paral
Pemoline	Cylert
Pentazocine	Talwin, Talwin NX, Talacen, Talwin Compound
Petrichloral	Pentaerythritol chloral, Periclor
Phenobarbital	Luminal, Donnatal, Bellergal-S
Phentermine	Ionamin, Fastin, Adipex-P, Obe-Nix, Zantryl
Pinazepam	Domar
Pipradrol	Detaril, Stimolag Fortis
Prazepam	Centrax
Quazepam	Doral, Dormalin
Sibutramine	Meridia
SPA	1-dimethylamino-1,2-diphenylethane, Lefetamine
Temazepam	Restoril
Tetrazepam	
Triazolam	Halcion
Zaleplon	Sonata
Zolpidem	Ambien, Stilnoct, Ivadal
Schedule V - (low potential for abuse compared to Schedule IV substances; some accepted medical use)	
Codeine preparations - 200 mg/100 ml or 100 gm	Cosanyl, Robitussin A-C, Cheracol, Cerose, Pediacof
Difenoxin preparations - 0.5 mg/25 ug AtSO4/du	Motofen
Dihydrocodeine preparations 10 mg/100 ml or 100 gm	Cophene-S, various others
Diphenoxylate preparations 2.5 mg/25 ug AtSO4	Lomotil, Logen
Ethylmorphine preparations 100 mg/100 ml or 100 gm	
Opium preparations - 100 mg/100 ml or gm	Parepectolin, Kapectolin PG, Kaolin Pectin P.G.
Pyrovalerone	Centroton, Thymergix

The Substance Abuse and Mental Health Services Administration (SAMHSA) sponsors an annual national survey on drug use and health. The most recent survey²¹ indicates there are 7.0 million (2.8 percent) persons aged 12 or older who used prescription-type psychotherapeutic drugs nonmedically in the past month. Of these, 5.2 million used pain relievers, an increase from 4.7 million in 2005.

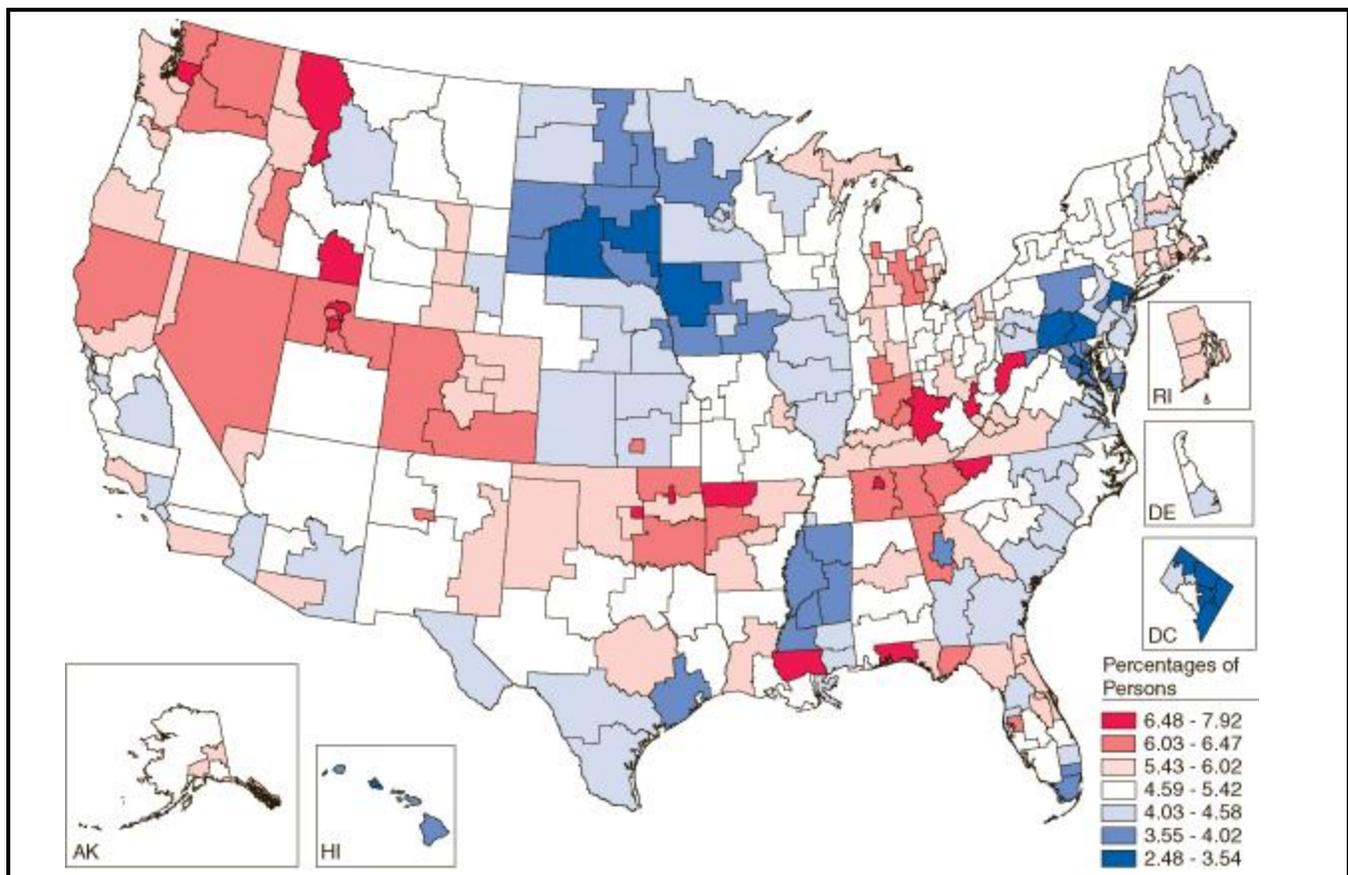
Of those 7 million people who used pain relievers nonmedically in a 12-month period, 55.7 percent reported they received the drug from a friend or relative for free. Another 9.3 percent bought the drugs from a friend or family member. Another 19.1 percent reported they obtained the drug through just one doctor. Only 3.9 percent got the pain relievers from a drug dealer or other stranger, and only 0.1 percent reported

²¹ 2006 National Survey on Drug Use and Health, U.S. Substance Abuse and Mental Health Services Administration, see <http://www.oas.samhsa.gov/nsduh/2k6nsduh/2k6Results.cfm#High> (last viewed January 30, 2010).

buying the drug on the Internet. Among those who reported getting the pain reliever from a friend or relative for free, 80.7 percent reported in a follow-up question that the friend or relative had obtained the drugs from just one doctor, while only 1.6 percent reported that the friend or relative had bought the drug from a drug dealer or other stranger.²²

National data indicate that the percent of the population using prescription pain relievers for nonmedical purposes in the past year ranged from a low of 2.48 percent in area of the District of Columbia to a high of 7.92 percent in northwest Florida. In Florida, for example: Palm Beach County measured 4.53 percent; Broward County measured 3.82 percent; Miami-Dade and Monroe Counties measured 3.59 percent; and Escambia, Okaloosa, Santa Rosa and Walton Counties combined measured 7.92 percent.²³

Figure 1. Nonmedical Use of Pain Relievers in the Past Year among Persons Aged 12 or Older, by Substate Region*: Percentages, Annual Averages Based on 2004, 2005, and 2006 NSDUHS



Source: Substance Abuse and Mental Health Services Administration, Office of Applied Studies. (June 19, 2008). The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006.

The Florida Medical Examiners Commission reports on drug-related deaths in Florida, and specifically tracks deaths caused by abuse of prescriptions drugs²⁴. According to the Commission, prescription drugs are found in deceased persons in lethal amounts more often than illicit drugs.²⁵ According to the Commission's data, 1,157 deaths in Florida from January 2009 through June 2009 were caused by prescription drugs, or about 6.3 deaths per day.²⁶

²² *Id.*

²³ Substance Abuse and Mental Health Services Administration, Office of Applied Studies, The NSDUH Report: Nonmedical Use of Pain Relievers in Substate Regions: 2004 to 2006, June 19, 2008, see <http://www.oas.samhsa.gov/2k8/pain/substate.cfm> (last viewed January 30, 2010).

²⁴ Florida Department of Law Enforcement, Medical Examiners Commission, Drugs Identified in Deceased Persons Interim Report, November 2009, see <http://www.fdle.state.fl.us/content/getdoc/036671bc-4148-4749-a891-7e3932e0a483/Publications.aspx> (last viewed January 30, 2010).

²⁵ *Id.*

²⁶ *Id.*

According to recent U.S. DEA statistics, the top 25 pain management clinics for dispensing of time release opioids and other pain relievers are all located in Florida.²⁷ The U.S. Drug Enforcement Administration identified the 50 practitioners who dispense the most Oxycodone in the country. All 50 top-dispensing practitioners are in Florida, and 33 are in Broward County.²⁸

Physician Dispensing of Oxycodone, by County²⁹

County	Units Oxycodone
Broward	6,584,200
Palm Beach	1,809,400
Miami-Dade	450,000
Pinellas	308,400
Hillsborough	277,300
Lake	220,400
Orange	111,200
Seminole	109,760

Physician Dispensing of Oxycodone in Palm Beach, Broward, Miami-Dade Counties, by Zip Code³⁰

Zip Code	Units Oxycodone
33311	1,235,700
33309	775,400
33334	727,600
33407	575,100
33313	442,800
33324	436,600
33009	396,000
33312	340,900
33020	329,000
33162	314,800
33301	285,900
33463	277,500
33417	241,700
33431	227,600
33325	198,800
33483	193,600
33323	186,800
33021	153,600
33487	151,200
33321	143,200
33445	142,700
33016	135,200
33024	130,200
33069	126,600
33023	122,800
33063	118,000
33073	111,900
33317	109,100
33308	107,000
33064	106,300

²⁷ Data drawn from the Automation of Reports and Consolidated Orders System, U.S. Department of Justice Drug Enforcement Administration, provided by the Florida Office of Drug Control via email March 22, 2009, on file with the Health Regulation Policy Committee, see <http://www.deadiversion.usdoj.gov/arcos/index.html> (last viewed January 30, 2010).

²⁸ Data drawn from the Automation of Reports and Consolidated Orders System, July-December 2008, U.S. Department of Justice Drug Enforcement Administration, provided by the Florida Office of Drug Control via email March 22, 2009, on file with the Health Regulation Policy Committee, see <http://www.deadiversion.usdoj.gov/arcos/index.html> (last viewed January 30, 2010)

²⁹ *Id.*

³⁰ *Id.*

In 2009, the State Attorney for the 17th Judicial Circuit (Broward County) empanelled a grand jury to consider the proliferation of pain clinics in Broward County and their effect on the community, and to make recommendations on what can be done to protect the public from the dangers of pain clinics. The grand jury interim report found that physicians in pain clinics dispense controlled substances directly to patients, rather than the patient going to a pharmacy to fill the prescription. Among other things, the grand jury recommended the state prohibit dispensing prescription drugs in pain clinics.³¹

Prescription Drug Monitoring Program

In the 2009 regular legislative session, the Legislature passed Senate bill 462 (Ch. 2009-198, Laws of Florida) to address the problem of prescription drug abuse. The bill:

- Required the Department of Health to establish a database of controlled substances dispensed to all patients in Florida;
- Required all pharmacies and all dispensing physicians are required to report all controlled substances dispensing to the Department within 15 days of dispensing;
- Required the Department to load the reported dispensing information into the database, and make it available to practitioners, regulators, and criminal justice entities upon their request;
- Established a registration requirement for pain clinics;
- Required the medical boards to adopt rules for the standards of medical practice in pain clinics
- Created a task force within the Executive Office of the Governor, chaired by the Office of Drug Control, to monitor and report on the implementation of the database; and
- Authorized the Office of Drug Control within the Executive Office of the Governor to establish a direct support organization to solicit public and private funding for the database.

As of January, 2010, the Department has implemented the clinic registration requirement, and the boards have begun rulemaking on the standards of practice. The Office of Drug Control has established the direct support organization. To date, \$400,000 has been generated to fund the database, via a grant from the U.S. Department of Justice awarded to the Department of Children and Families prior to the passage of the bill. Current projections of the cost for the program are \$449,665 in non-recurring first year costs, and \$480,486 in recurring annual costs.³²

Effect of Proposed Changes

The bill amends s. 465.0276, F.S. to prohibit practitioners from dispensing more than a 72-hour supply of controlled substances listed in Schedules II, III, and IV. The bill does not prohibit physicians from prescribing controlled substances. Under the bill's provisions, patients who receive prescriptions for controlled substances would fill them at pharmacies, rather than in physician offices or clinics.

The bill exempts controlled substances dispensed in the health care system of the Department of Corrections. Hospitals and other facilities dispensing through institutional pharmacies would be unaffected by the bill.

The bill provides an effective date of July 1, 2010.

B. SECTION DIRECTORY:

Section 1. Amends s. 465.0276, F.S., related to dispensing practitioners.

Section 2. Provides an effective date of July 1, 2010.

³¹ The Proliferation of Pain Clinics in South Florida, Interim Report of the Broward County Grand Jury, Circuit Court of the Seventeenth Judicial Circuit, November 19, 2009.

³² PL2009-198 Implementation of the Prescription Drug Monitoring Program & Pain Clinic Registration Florida Department of Health, Florida Department of Health, presentation to the House Health Regulation Policy Committee, January 12, 2010; Prescription Drug Monitoring Program PL2009 – 198 Implementation Status Plan, Florida Office of Drug Control, Executive Office of the Governor, presentation to the House Health Regulation Policy Committee, January 12, 2010.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

None.

2. Expenditures:

None. According to the Department of Health, which regulates dispensing practitioners, House Bill 225 has no fiscal impact on the Department.

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

None.

2. Expenditures:

None.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

None identified.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

This bill does not appear to require counties or municipalities to take an action requiring the expenditure of funds, reduce the authority that counties or municipalities have to raise revenue in the aggregate, nor reduce the percentage of state tax shared with counties or municipalities.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

No additional rule-making authority is required to implement the provisions of the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/COUNCIL OR COMMITTEE SUBSTITUTE CHANGES